

TRANSMITTAL LETTER TO THE UNITED STATES  
DESIGNATED/ELECTED OFFICE (DO/EO/US)  
CONCERNING A FILING UNDER 35 U.S.C. 371

1473-070

U.S. APPLICATION NO. (If known, see 37 CFR 1.5

10/018988

INTERNATIONAL APPLICATION NO.

PCT/AU00/00936

INTERNATIONAL FILING DATE

7 August 2000 (07.08.2000)

PRIORITY DATE CLAIMED

6 August 1999 (06.08.1999)

TITLE OF INVENTION

## IMPROVED COCHLEAR IMPLANT PACKAGE

APPLICANT(S) FOR DO/EO/US

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Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

1. ☒ This is a **FIRST** submission of items concerning a filing under 35 U.S.C. 371.
2. ☐ This is a **SECOND** or **SUBSEQUENT** submission of items concerning a filing under 35 U.S.C. 371.
3. ☐ This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (21) indicated below.
4. ☐ The US has been elected by the expiration of 19 months from the priority date (Article 31).
5. ☒ A copy of the International Application as filed (35 U.S.C. 371(c)(2))
- a. ☐ is attached hereto (required only if not communicated by the International Bureau).
- b. ☒ has been communicated by the International Bureau.
- c. ☐ is not required, as the application was filed in the United States Receiving Office (RO/US).
6. ☐ An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)).
- a. ☐ is attached hereto.
- b. ☐ has been previously submitted under 35 U.S.C. 154(d)(4).
7. ☒ Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3))
- a. ☐ are attached hereto (required only if not communicated by the International Bureau).
- b. ☐ have been communicated by the International Bureau.
- c. ☐ have not been made; however, the time limit for making such amendments has NOT expired.
- d. ☒ have not been made and will not be made.
8. ☐ An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).
9. ☒ An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)).
10. ☒ An English language translation of the annexes of the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).

## Items 11 to 20 below concern document(s) or information included:

11. ☒ An Information Disclosure Statement under 37 CFR 1.97 and 1.98.
12. ☒ An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.
13. ☒ A FIRST preliminary amendment.
14. ☐ A SECOND or SUBSEQUENT preliminary amendment.
15. ☐ A substitute specification.
16. ☐ A change of power of attorney and/or address letter.
17. ☐ A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 35 U.S.C. 1.821 - 1.825.
18. ☒ A second copy of the published international application under 35 U.S.C. 154(d)(4).
19. ☐ A second copy of the English language translation of the international application under 35 U.S.C. 154(d)(4).
20. ☒ Other items or information: **Return receipt postcard; Copy of PCT Notification Concerning Submission of Transmittal of Priority Doc; Check \$**



**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**  
**UNITED STATES RECEIVING OFFICE OF THE**  
**PATENT COOPERATION TREATY (35 USC §371)**

U.S. Applicant : CLARKE, Graeme Milbourne *et al*  
U.S. Serial No. : To Be Assigned  
U.S. Filing Date : Herewith  
International Applicant : THE UNIVERSITY OF MELBOURNE  
International Application No. : PCT/AU00/00936  
International Filing Date : 07 August 2000 (07.08.2000)  
Earliest Claimed Priority : 06 August 1999 (06.08.1999)  
Title : IMPROVED COCHLEAR IMPLANT PACKAGE  
Examiner : To Be Assigned  
Group Art Unit : To Be Assigned

Box **PCT**  
Attn: National Phase Processing Division  
Assistant Commissioner for Patents  
Washington, DC 20231

**CERTIFICATE OF EXPRESS MAIL UNDER 37 CFR §1.10**

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*Belinda J. Hunter*  
Belinda J. Hunter

**PRELIMINARY AMENDMENT**

S I R :

Prior to substantive examination, kindly amend the subject application as follows:

**IN THE CLAIMS:**

Amend claims 3-6 and 8 as shown in the following section CLAIMS IN CLEAN FORM.

## CLAIMS IN CLEAN FORM

3. The implant package of claim 1, wherein the flexibility of the flexible connection between the protective housing and the protective casing is such a to allow changes in head shape as the patient grows.

4. The implant package of claim 1, wherein the flexible connection is made from a material having memory so that the coupling retains its shape after installation into the mastoid cavity.

5. The implant package of claim 1, wherein the implant package is electrically coupled to the electrode array.

6. The implant package of claim 1, wherein the implant package is electrically coupled to the receiving and/or transmitting coil.

8. The implant package of claim 1, wherein the implant package is a receiver-stimulator package for a cochlear implant.

REMARKS

Amendments have been made to the claims in order to eliminate multiple dependencies. No new matter is being added hereof.

Dated: December 19, 2001  
New York, New York

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VERSION OF MARKINGS TO SHOW CHANGES MADE  
CLAIMS

3. The implant package of claim 1 [or 2], wherein the flexibility of the flexible connection between the protective housing and the protective casing is such a to allow changes in head shape as the patient grows.

4. The implant package of [any preceding] claim 1, wherein the flexible connection is made from a material having memory so that the coupling retains its shape after installation into the mastoid cavity.

5. The implant package of [any preceding] claim 1, wherein the implant package is electrically coupled to the electrode array.

6. The implant package of [any preceding] claim 1, wherein the implant package is electrically coupled to the receiving and/or transmitting coil.

8. The implant package of [any preceding] claim 1, wherein the implant package is a receiver-stimulator package for a cochlear implant.

V/PRTS

531 Rec'd PCT

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19 DEC 2001

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## IMPROVED COCHLEAR IMPLANT PACKAGE

### Field of the Invention

- This invention relates to improvements in cochlear implants, and more particularly to improvements relating to the shapes of implant packages, e.g.
- 5 receiver-stimulator packages, to enable the cochlear implant to be positioned in a patient in a more desirable location than the location presently used.

### Background of the Invention

- Present cochlear implant receiver-stimulators are placed in a patient by
- 10 drilling a bed into and through the posterior section of the mastoid bone lying behind the ear. The bed is usually made by drilling the bone down to the lining of the brain or dura mater. The receiver-stimulator of the Nucleus cochlear implant made by Cochlear Limited has a receiver-stimulator package made from titanium which houses the stimulation electronics and which is fitted into the
- 15 bed in the mastoid bone. A receiver coil extends from the back end of the package and lies superficial to the bone. Other cochlear implants have included packages made from ceramic material and these are usually placed completely within a bed drilled down to the lining of the brain, especially in young children.
- 20 In young children, placing either of the above packages in the mastoid bone some distance behind the ear can lead to the packages creating an external swelling, which can be unsightly. More importantly, such placements of the package can lead to serious damage caused by excessive impact to the head in the area adjacent the implant. Such impact can lead to fractures of the electrode
- 25 where it exits the package, or cracking or damage of the package itself. In addition, because the packages are placed in this particular location, especially where a bed is drilled down to the lining of the brain, it is possible for excessive impact to cause the package to enter the cranial cavity and damage structures including the brain.

30

Summary of the Invention and Object

It is an object of the present invention to provide an improved implant package for a cochlear implant shaped to be received in a more desirable location within the skull of the patient.

- 5 The invention provides an implant package for a cochlear implant, said implant package including stimulator electronics contained within a protective housing and being operably coupled to an electrode array adapted for insertion into the cochlea of the patient, and being further operably coupled to a receiving and/or transmitting coil enclosed within a protective casing, said protective
- 10 housing being dimensioned and shaped to be capable of location within the mastoid cavity of the patient nearer to the entry point of the electrode array to the cochlea, said further coupling being contained in a flexible connection between the protective housing and the protective casing.

- By positioning the implant electronics housing in this way, the housing is
- 15 less exposed to the risk of trauma caused by excessive blows to the head as it lies below the surface of the skull bone and is therefore less susceptible to a direct blow, and is additionally protected by the overlying pinna. The flexible coupling enables the coil to be placed in an optimal position and, depending on the anatomy and the age of the person, over time the coupling would adjust to
- 20 any changes in head shape.

Advantageously, the implant package is electrically coupled to the electrode array and is further electrically coupled to the receiving and/or transmitting coil.

- In a preferred form, the flexible coupling is made from a material having
- 25 memory so that the coupling retains its desired shape when installed in the mastoid cavity. The flexible connection can include one or more flexible arms which contain the electrical leads for connecting the implant electronics in the protective housing to the transmitter/receiver coil. While two arms are shown in the preferred embodiment, one arm may have the advantage of reducing the
- 30 inductive effects between the leads within the arms and the magnetic coil of the transmitter/receiver.



The implant package is preferably a receiver-stimulator package for a cochlear implant.

#### Brief Description of the Invention

5 A preferred embodiment of the invention will now be described with reference to the accompanying drawings in which:

Figure 1 schematically illustrates one embodiment, and

Figure 2 is a schematic cross section illustrating the positioning of the protective casing and the protective housing relative to the ear canal, the  
10 mastoid cavity and the drilled bed in the skull.

#### Description of the Preferred Embodiment

Anatomical dissections show that there is a gutter lying between the sigmoid sinus, posterior osseous ear canal, the mastoid tip and the floor of  
15 middle fossa where an appropriately shaped housing for the implant unit can be placed so that the housing is not exposed above the surface of the bone.

As illustrated in the drawings, the housing 2 comprises a narrow elongate rectangular housing having rounded ends, somewhat like a flattened ovoid or lozenge shape, which is received in the mastoid cavity C referred to above  
20 adjacent the ear canal C<sub>1</sub>. The housing 2 may be made from titanium, similar to the Nucleus device, or from cast or moulded ceramic material.

As described above, the protective housing 2 for the implant electronics, in this case the receiver-stimulator electronics, is connected by suitable leads 4, 5 to a transmitter/receiver coil 3, the leads 4, 5 being contained within flexible  
25 arms 6, 7 of inert material such as silicone rubber. If desired, the arms 6, 7 can be formed from or incorporate a material having memory so that the arms retain their manufactured shape after installation.

The coil 3 is enclosed within a protective casing 8, which is received in a drilled bed B<sub>3</sub> in the mastoid bone behind the ear. Suitably shaped beds B<sub>1</sub>, B<sub>2</sub>  
30 connecting the mastoid cavity and the drilled bed B<sub>3</sub> with the skull S receive the flexible arms 6, 7 containing the connecting leads 4, 5. A further lead 9 extends

from the housing 2 into the ear canal C<sub>1</sub> through a window W and terminates in an electrode array (not shown) which is implanted in the cochlea.

Since the receiver-stimulator housing 2 is located in the mastoid cavity C, below the surface of the bone, it is less susceptible to damage and is  
5 protected and hidden by the overlying pinna. The flexible arm(s) 6, 7 allow optional positioning of the coil and permit changes in head shape.

The receiver-stimulator electronics, the transmitter/receiver coil, and the electrode array for implantation in the cochlea of the patient are configured in accordance with the patent literature relating to the cochlear implant technology  
10 and do not form any part of the present invention.

While one preferred shape for the protective housing has been described above, it will be appreciated that different shapes, which are capable of lying wholly within the gutter forming part of the mastoid cavity, can be adopted without departing from the essence of the invention defined above.

It is also envisaged that whilst the above embodiment is described with  
15 reference to a conventional cochlear implant system, i.e. one with a receiver-stimulator that receives coded signals from an external unit and provides stimulation to the cochlea accordingly, the present invention could equally be applied to a totally implanted cochlear implant system. In such a system the  
20 implant unit has the capability of functioning without the need for any external devices, at least for a defined period of time.

## CLAIMS:

1. An implant package for a cochlear implant, said implant package including stimulator electronics contained within a protective housing and being operably coupled to an electrode array adapted for insertion into the cochlea of the patient, and being further operably coupled to a receiving and/or transmitting coil enclosed within a protective casing, said protective housing being dimensioned and shaped to be capable of location within the mastoid cavity of the patient nearer to the entry point of the electrode array to the cochlea, said further coupling being contained in a flexible connection between the protective housing and the protective casing.
2. The implant package of claim 1, wherein the flexible connection facilitates optimal positioning of the coil, depending on the anatomy and age of the patient.
3. The implant package of claim 1 or 2, wherein the flexibility of the flexible connection between the protective housing and the protective casing is such as to allow changes in head shape as the patient grows.
4. The implant package of any preceding claim, wherein the flexible connection is made from a material having memory so that the coupling retains its shape after installation into the mastoid cavity.
5. The implant package of any preceding claim, wherein the implant package is electrically coupled to the electrode array.
6. The implant package of any preceding claim, wherein the implant package is electrically coupled to the receiving and/or transmitting coil.
7. The implant package of claim 6, wherein the flexible connection includes one or more flexible arms containing leads which electrically connect the implant electronics to the receiving and/or transmitting coil.
8. The implant package of any preceding claim, wherein the implant package is a receiver-stimulator package for a cochlear implant.

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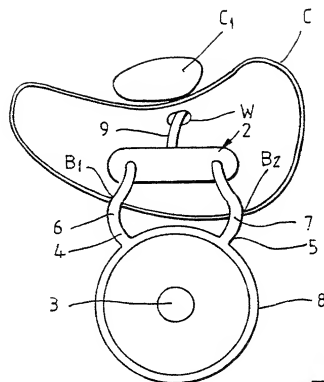


Fig. 1.

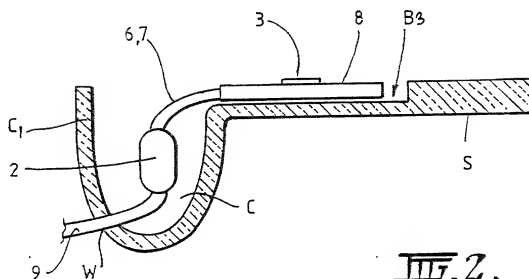


Fig. 2.

## Combined Declaration and Power of Attorney

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name.

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled

### IMPROVED COCHLEAR IMPLANT PACKAGE

the specification of which

(check one) ☒ is attached hereto. ☒ was filed on 7 August 2000, as United States Application Serial No. \_\_\_\_\_ or PCT International Application No. PCT/AU00/00936, and was amended on \_\_\_\_\_ (if applicable).

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to patentability as defined in Title 37, Code of Federal Regulations, ' 1.56.

I hereby claim foreign priority benefits under Title 35, United States Code, ' 119 (a)-(d) or 365(b) of any foreign application(s) for patent or inventor's certificate, or 365(a) of any PCT international application which designated at least one country other than the United States of America, or Title 35, United States Code, ' 371 listed below and have also identified below, by checking the appropriate box, any foreign application for patent or inventor's certificate, or of any PCT application having a filing date before that of the application on which priority is claimed:

#### Prior Foreign Application(s)

Priority claimed

<u>PQ2071</u>	<u>Australia</u>	<u>6 August 1999</u>	<input checked="" type="radio"/>	<input type="radio"/>
(Number)	(Country)	Day/month/year filed	Yes	No
			<input type="radio"/>	<input type="radio"/>
(Number)	(Country)	Day/month/year filed	Yes	No

I hereby claim the benefit under Title 35, United States Code, ' 119(e) of any United States provisional application(s) listed below:

(Application No.) (Filing Date)

(Application No.) (Filing Date)

I hereby claim the benefit under Title 35, United States Code, ' 120 of any United States application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of Title 35, United States Code, ' 112, I acknowledge the duty to disclose information which is material to patentability as defined in Title 37, Code of Federal Regulations, ' 1.56 which occurred between the filing date of the prior application and the national or PCT international filing date of this application:

(Application No.) (Filing date) (Status - patented, pending, abandoned)

(Application No.) (Filing date) (Status - patented, pending, abandoned)

And I hereby appoint

12

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whose address is Gottlieb, Rackman & Reisman, P.C., 270 Madison Avenue, New York NY 10016-0601 (telephone (212) 684-3900), jointly and severally, as my attorneys and/or agents, with full power of substitution and revocation, to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith.

Direct all correspondence and telephone calls to: Tiberiu WEISZ, Esq. at the address and telephone number shown above.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

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